

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/02, 2/06, 2/01	A1	(11) International Publication Number: WO 96/14808 (43) International Publication Date: 23 May 1996 (23.05.96)
---	----	---

(21) International Application Number: PCT/US95/14535
(22) International Filing Date: 8 November 1995 (08.11.95)
(30) Priority Data: 08/336,875 9 November 1994 (09.11.94) US
(71) Applicant: ADVANCED CARDIOVASCULAR SYSTEM, INC. [US/US]; 3200 Lakeside Drive, Santa Clara, CA 95052-8167 (US).
(72) Inventors: BROWN, Peter, S.; 57 Dalma Drive, Mountain View, CA 94041 (US). CANNON, James, M., Jr.; 3032 Cameron Way, Santa Clara, CA 95051 (US). ORTH, Geoffrey, A.; 246 Columbus Street, El Granada, CA 94018 (US).
(74) Agents: KOENIG, Nathan, P.; Crosby, Heafy, Roach & May, 1999 Harrison Street, Oakland, CA 94612-3573 (US) et al.

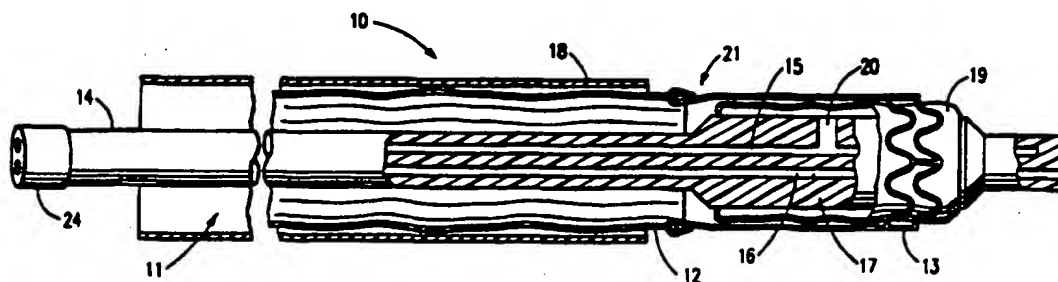
(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: DELIVERY CATHETER AND GRAFT FOR ANEURYSM REPAIR



(57) Abstract

This invention provides a graft delivery system and methods for its use comprising a prosthetic graft (12) secured to an expandable anchoring member, such as a stent (13), by a butt-joint attachment means (21) to minimize the system's profile. The delivery system employs a catheter (11) with a relatively small diameter shaft (14) for flexibility and a relatively large diameter (14) delivery base (17) for supporting expansion of the anchoring member. The butt-joint attachment means comprises any means suitable to secure the graft to the anchoring member when deployed within the patient's vasculature and allows the anchoring member and graft to expand during deployment. In a preferred embodiment, the delivery system is configured so that the expansion of the anchoring member pulls the distal end of the graft over the proximal end of the anchoring member and the final expansion of the anchoring member seals the distal end of the graft (12) between the proximal end of the anchoring member and the vessel (20). One preferred method of use is to deploy a second anchoring member (31) coaxially within the already deployed first anchoring member and graft assembly, overlapping at least the distal end of the graft in order to further secure the graft and minimize flow by.

BEST AVAILABLE COPY

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LJ	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

DELIVERY CATHETER AND GRAFT FOR ANEURYSM REPAIR

BACKGROUND

5 This invention relates to the delivery and placement of vascular grafts, and in particular, to a method and system for the repair of abdominal aortic aneurysms.

 An aneurysm is a sac resulting from abnormal dilation of the artery wall and is often associated with arteriosclerotic disease. Unless treated, an
10 aneurysm can rupture, leading to severe and often fatal hemorrhaging.

 Treating an aortic aneurysm generally involves transplanting a prosthetic graft to bridge the affected section of the aorta. Surgical implantation of the graft is possible but this treatment causes considerable trauma, results in high mortality and morbidity and, even when completely successful, requires a
15 lengthy recuperation period. Due to the difficulty of the operation, direct surgical replacement is even less attractive when it must be performed on an emergency basis after the aneurysm has ruptured.

 A less invasive alternative involves the use of a catheter to effect intraluminal delivery of a graft. Prior art graft delivery systems, such as
20 disclosed in EP 0 461 791 A1 (Barone et al.), employ a graft with expandable portions that anchor the graft in the aorta. Often, the systems use an inflatable balloon on the delivery catheter to expand the anchoring portion of the graft as disclosed in United States Pat. No. 5,275,622 (Lazarus et al.) which is hereby incorporated in its entirety by reference thereto. This latter

example requires the use of a bulky capsule to store the graft and a complicated pushrod system to deploy the graft.

The success of a percutaneous vessel repair depends in large part on getting the graft to the location of the vasculature in need of repair and
5 deploying the graft effectively. A difficulty associated with graft deployment is blood flow-by which occurs when blood can pass between the graft and the patient's vessel, bypassing the graft.

Although the referenced prior art systems and others employ many different stent and graft configurations, none are completely satisfactory.
10 The principle limitation of the prior art systems is their size. They typically require a delivery catheter having a diameter of approximately 28-30 French (9.3 to 10 mm). Although it is desirable to introduce grafts through the femoral artery, its inner diameter is only about 4 to 6 mm. Thus, the size of the prior art devices restricts them to introduction through upper femoral
15 sites, where access may be difficult. Further, these systems are too bulky and inflexible to access many regions of a patient's vasculature. Accordingly, there is a need for a delivery catheter and graft system capable of introduction through a smaller opening while maintaining the ability to reliably and securely deploy the graft.

20

SUMMARY OF THE INVENTION

This invention provides a method and graft delivery system which minimizes the system's profile to aid its placement and to permit access to more areas of a patient's vasculature. The system generally comprises a

prosthetic graft secured to an expandable anchoring member, such as a stent, by a butt-joint attachment means. The delivery system employs a catheter with a relatively small diameter flexible shaft and a relatively large diameter delivery base to support expansion of the anchoring member.

- 5 The graft is attached to the anchoring member in a suitable manner and the anchoring member and graft assembly are loaded on the delivery catheter in a precise configuration to minimize the system's profile. Since anchoring members have a finite degree of expansion, an anchoring member which has an expanded diameter large enough to be securely deployed within a given
- 10 vessel has a minimum diameter corresponding to the anchoring member's most compressed state. To effectively expand the anchoring member, the delivery system must have a diameter large enough to support the anchoring member in its most compressed state. Accordingly, the catheter comprises a delivery base having a means to expand the anchoring member and a
- 15 diameter which approximates the anchoring member's minimum compressed diameter to support the anchoring member during deployment. The remainder of the catheter shaft has a smaller diameter than the delivery base to provide flexibility. The anchoring member and graft are coaxially threaded over the delivery catheter and positioned with the anchoring member over the delivery
- 20 base and the graft over the catheter shaft just proximal to the delivery base. In order to minimize the system's profile, the graft does not overlap the delivery base because its effective wall thickness is much greater than the anchoring member's. Accordingly, the anchoring member and graft have a

butt-joint attachment prior to deployment to avoid overlap between the graft and the delivery base.

The butt-joint attachment means comprises any means suitable to secure the graft to the anchoring member when deployed within the patient's vasculature and allows the anchoring member and graft to expand during deployment. The attachment also minimizes the flow by of blood once the graft and anchoring member are deployed. In a preferred embodiment, the delivery system is configured so that the expansion of the anchoring member pulls the distal end of the graft over the proximal end of the anchoring member and the final expansion of the anchoring member seals the distal end of the graft between the proximal end of the anchoring member and the vessel. In other embodiments, a plurality of staples extend from the anchoring member and attach the graft via hooks, T-bars, or the like. Alternatively, a plurality of ribbons extending from the graft are woven through the anchoring member. This invention also comprises the method of deploying a second anchoring member within the deployed graft and first anchoring member to overlap at least the upstream edge of the graft, securing and sealing the graft within the vessel to minimize or prevent flow by.

The graft delivery systems of this invention provide a means for attaching the graft to the anchoring member and a delivery catheter which minimize the profile of the system. While the invention has been described primarily with respect to a system comprising the catheter loaded with an anchoring member and graft, it includes the delivery catheter alone, kits

which include unassembled catheters, anchoring members and grafts, and methods of use.

BRIEF DESCRIPTION OF THE DRAWINGS

5 FIG. 1 is a longitudinal cross-sectional view of a delivery catheter and graft system embodying features of this invention.

 FIG. 2 is an elevational view of a prosthetic assembly of the invention showing the hook and staple attachment of the anchoring member to the graft in their expanded states. FIG. 2a is transverse cross-sectional view of
10 graft and attachment taken at 2a-2a of Fig 2.

 FIG. 3 is an elevational view of a prosthetic assembly of the invention showing the hook and staple attachment of the anchoring member to the graft in their compressed states. FIG. 3a is transverse cross-sectional view of graft and attachment taken at 3a-3a of Fig 3.

15 FIGs. 4a-c illustrate a prosthetic assembly of the invention having a graft overlapping attachment of the anchoring member, showing the compressed, expanding and expanded states, respectively. FIG. 4d illustrates an alternate embodiment of the anchoring member.

 FIGs. 5-6 illustrate prosthetic assemblies of the invention having
20 attachment means employing graft ribbons.

 FIG. 7 illustrates a prosthetic assembly of the invention having attachment means employing wires woven into the graft.

 FIG. 8 illustrates a method of the invention using a second anchoring member to further seal and secure the graft.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 is a elevational view in section illustrating a catheter system 10 embodying features of the invention which generally comprises a catheter 11 with an aortic graft 12 attached to an expandable anchoring member, stent 13, loaded for delivery. The catheter 11 comprises a flexible catheter shaft 14 with proximal and distal ends, an inflation lumen 15 and a guidewire lumen 16. A delivery base 17 is located on a distal portion of the catheter shaft 14 and has a substantially larger outer diameter than the adjacent catheter shaft 14. A thin-walled retractable sheath 18 is slidably disposed over the catheter 11 and configured so that it can cover the stent 13 and attached graft 12 during introduction and placement of the catheter system 10 and be withdrawn once they are in an appropriate position within the patient.

In this embodiment, the means for expanding stent 13 comprises an inflatable balloon 19 positioned over delivery base 17 and in fluid communication with the inflation lumen 15 through inflation passage 20, but other means or the use of a self-expanding anchoring member are suitable.

The distal end of the graft 12 is secured the proximal end of stent 13 by a butt-joint attachment means 21. Means of attachment include employing hooks and staples, a graft overlapping anchoring member configuration, graft ribbons or woven wires as discussed below regarding FIGs. 2-7. In general, attachment of graft 12 to stent 13 provides sufficient support to retain the graft 12 at the desired location within a patient's vasculature once stent 13 is deployed. There are also sufficient points of

attachment to support the graft 12 in an open position once graft 12 and stent 13 are expanded, helping seal the graft 12 in the vessel and minimizing flow by of blood.

As shown in FIGs. 2-3, the effective wall thickness of stent 13 does not change between the pre-expanded and expanded states. On the other hand, the graft 12 bunches when compressed to conform to the catheter shaft 14 and forms overlaps and pleats, effectively increasing its wall thickness as shown in FIG. 4a. stent 13 and graft 12 are coaxially threaded over the catheter 11 so that stent 13 is positioned over the increased diameter delivery base 17 and the graft 13 is positioned over the narrow diameter distal section catheter shaft 14 proximal to the delivery base as shown in FIG. 1. Graft 12 and stent 13 have a butt-joint attachment prior to deployment, so that graft 12 does not overlap with the stent 13 or the delivery base 17. Employing a butt-joint attachment between the anchoring member and the graft saves approximately 5.1 mm from the diameter of system 10 over conventional systems. Accordingly, the delivery catheters of this invention have an insertion diameter of less than 7 mm and preferably about 6 mm. This allows system 10 to present a small outer diameter for introduction into the body, preferably through the femoral artery, while maintaining the flexibility necessary to pass through tortuous regions of a patient's vasculature.

The diameter of the delivery base 17 should be between about 1.1 and 4.0 times greater than the diameter of the catheter shaft 14 and preferably between about 2.0 to 2.5 times greater in order to provide support for the

expansion of stent 13. Generally, the length of the delivery base 17 preferably is at least as long as the inflatable balloon 19 and may be up to two times or more the length of the balloon 19. The balloon 19 may be shorter or longer than the stent 13. In one embodiment, a 5F catheter shaft (1.7 mm) is coupled with a 12F delivery base (4 mm) which is about 13 mm longer than the anchoring member.

Preferably, the stent 13 is a Bronco® stent, available from Advanced Cardiovascular Systems, Inc. of Santa Clara, CA. As shown in FIG. 3, for example, it comprises a framework having a series circular expanding members 22 joined by tie bars 23 to form an open cylinder. The expanding members 22 have a generally sinusoidal shape with the sinusoid forming the wall of the cylinder. When expanded, the diameter of the expanding members 22 increases as the amplitude of the sinusoid flattens out as shown in FIG. 2. As a result of this design, the length of stent 13 does not change substantially when expanded.

Other means of expanding the stent 13 may be employed. Stent 13 could be constructed from shape-memory materials causing it to revert to its expanded shape at body temperatures. In such embodiments, thin-walled sheath 18 would restrain anchoring member 12 until properly positioned.

The proximal end of catheter shaft 14 has a cap 24 bonded the end to provide access to inflation lumen 15 and guidewire lumen 16. The configuration of cap 24 allows it to mate with a multi-arm adaptor (not shown) that supplies inflation fluid and allows guidewire control in a conventional manner. Cap 24 is preferably formed from metal, although other

materials such as plastics are suitable. The diameter of cap 24 allows the compressed graft 12 and stent 13 to be threaded over the proximal end of catheter shaft 14, since when graft 12 is compressed, it will not fit over delivery base 17.

5 FIGs. 2-3 detail the hook and staple butt-joint attachment means 21 of the graft 12 to the stent 13. A plurality of staples 25 extend from the proximal end of the anchoring member and engage the graft with a hook 26 or a T-bar 27 as shown in FIG. 4. Other suitable means for engaging the graft 13 may be located at the end of each staple 25. As shown in FIGs. 2-
10 3, the staples 25 are separate elements which are attached to the proximal end of stent 13 by suitable means, such as welding, bonding or bending the end of each staple 25 around the stent 13. Alternatively, the stent 13 may be configured so that it has integral extensions of the anchoring member shaped in the form the staples which may be use to connect the stent 13 to
15 the graft 12.

 FIGs. 4a-c illustrate an alternate, preferred means of attachment. In this embodiment, staples 25 are attached to an expanding member 22a near the proximal end of the stent 13, leaving at least one expanding member 22b more proximal to the graft 12. T-bars 27 at the ends of the staples 25
20 engage a portion of the distal end of the graft 12. The staples 25 are attached to the portion of the expanding member 22a closest to the graft 12. As depicted in FIGs. 4b-c, the sinusoidal expanding member 22a flattens out during expansion. Since the overall length of the stent 13 does not change during expansion, the distal end of graft 12 is pulled towards and over at

least one expanding member 22b at the proximal end of stent 13. The expansion of expanding member 22b acts to seal the opening of the graft 12 to the patient's vessel. In one embodiment, the axial distance between the point of attachment of tie bar 23 and staples 25 to expanding member 24b is 5 4.45 mm when the stent 13 is compressed. When expanded, this distance is reduced to 2.92 mm. The expansion produces about 1.5 mm of movement to pull distal end of graft 12 over the proximal end of stent 13.

Stent 13 in FIG. 4d illustrates a configuration to maximize the relative motion of the graft 12. Sinusoidal expanding member 22c has varying 10 amplitudes with the greatest amplitude oriented towards the graft 12. Accordingly, the flattening of this sinusoid when stent 13 is expanded pulls the staples 25 a relatively greater distance than expanding members without varying amplitudes.

As shown in FIG. 4b, means for differential expansion expands the 15 distal end of stent 13 before the proximal end. This allows graft 12 to be pulled over expanding member 22b before it expands. In one embodiment, stent 13 is formed so that the proximal portion comprises a heavier gauge material than the distal portion so that the distal portion expands before the proximal portion. In other embodiments, the inflatable balloon 19 may be 20 formed from material of varying resilience so that the distal portion of the balloon expands before the proximal portion. A multi-balloon system allowing sequential expansion may also be employed. Differential expansion in embodiments comprising a self-expanding anchoring member may be achieved in many suitable ways. For example, in embodiments where stent

13 is formed from NiTi alloys, the expanding members 22 could be formed from alloys having slightly different transition temperatures in the distal portion and the proximal portion. Alternatively, the restraining sheath 18 could be withdrawn from the distal portion of stent 13 while still restraining
5 the proximal portion.

FIGs. 5-7 show alternative anchoring member to graft attachments. In FIGs. 5 and 6, portions of the distal end of graft 12 have been removed to leave a plurality of graft ribbons 28 disposed radially around the distal end of graft 12. In FIG. 5, the ribbons 28 are wound around the tie bars 23 of stent
10 13. In FIG. 6, the ribbons 28 are wound in and out of adjacent expanding members 23 on stent 13. In both situations, only a small portion of graft 12 (the ribbons 28) is used in the attachment, so the overlap of these portions with stent 13 and delivery base 17 when loaded on catheter system 10 does not substantially increase the system's profile. Instead of being integral
15 extensions of the graft, graft ribbons 28 may also be separate elements attached to graft 12 by any suitable means. In FIG. 7, a plurality of wires 29, preferably stainless steel, are woven into graft 12. The free ends of the wires 29 are attached to stent 13 by any suitable means, including welding, soldering, bonding and tying.

20 The anchoring members may be formed from any suitable material, including tantalum, stainless steel, other metals and polymers and when employing a self-expanding anchoring member, shape-memory metals such as NiTi alloys. The anchoring member may also be coated with a polymer or seeded with endothelial cells to further inhibit thrombosis. Generally, the

anchoring member is formed in its pre-expanded state. Once attached to the graft and positioned over the delivery base 17, the anchoring member may be crimped down to a slightly smaller inner diameter to secure the assembly during introduction and to further reduce the delivery diameter. Anchoring member configurations are suitable so long as they are self supporting within the aortic passageway while providing suitable means for attachment to hold the graft in place.

The grafts of this invention are intact tubes, preferably constructed of a synthetic yarn, monofilament or multifilament, formed from materials such as polyesters (including Dacron®), polytetrafluoroethylene (PTFE), polyurethane and nylon. Dacron® in particular, a multifilament composed of polyethylene terephthalate (PET), has been shown to be suitable and may promote formation of intima. The synthetic material may be woven or knit. The woven grafts are generally stronger and less porous while knit grafts are softer and more porous. Additionally, the surface of the synthetic material may be texturized and woven or knit to form a velour surface which generally facilitates growth of tissue from the surrounding lumen through the velour loops to help secure the graft. If desirable, the graft may be bifurcated.

The catheter shaft 14 may be formed from any suitably flexible material, such as pseudoelastic metals (e.g. NiTi alloys) and a wide range of conventional polymers. Preferably, the catheter shaft 14 is formed from an extrudable polymer such as polyethylene (PE). The delivery base 17 may be formed as an integral part of the shaft 14 as shown or may be a separate element which is attached to the shaft in any suitable manner.

The inflatable balloon 19 preferably may be an essentially non-distensible inflatable balloon to provide the degree of expansion control and durability necessary to effectively anchor the anchoring member. The balloon may be formed from any suitable material such as PE, polyethylene

5 terephthalate (PET) or nylon or other polyamide.

The use of the catheter system 10 generally follows conventional procedures. In particular, a guidewire (not shown) is backloaded into guidewire receiving lumen 16 of the catheter 11 with sheath 18 extending over the compressed and loaded graft 12 and attached stent 13. The

10 catheter system 11 and guidewire are percutaneously introduced by means of conventional cut down techniques in the patient's arterial system, generally through the femoral artery. The guidewire is advanced out delivery catheter 11 and up the aorta via fluoroscopic imaging until it crosses the aneurysm. Then the catheter 11 is advanced over the guidewire until the stent 13 is

15 positioned within the aorta adjacent to healthy tissue upstream from the aneurysm. The sheath 18 is retracted to expose the stent 13 and the graft 12. The balloon 19 is inflated to expand the stent 13 to anchor it in the aorta. The balloon 19 is then deflated and the catheter 11 is removed, leaving the anchored anchoring member and graft in place.

20 Once deployed, the attachment of the graft to the anchoring member and the sealing of the graft to the patient's vessel may be improved by deploying a second anchoring member as illustrated in FIG. 8. Once the first stent 13 and attached graft 12 are deployed within a patient's vessel 30, a second anchoring member 31 without an attached graft is deployed coaxially

within the stent 13 and graft 12. The second anchoring member overlaps the attachment between first stent 13 and graft 12 to sandwich the graft 12 against the vessel, further minimizing flow by. Preferably, the second anchoring member 31 is approximately two times the length of the first stent 5 13 and extends past the distal end of the first stent 13.

The invention has been described herein primarily with reference to presently preferred embodiments. However, it should be recognized that various modifications and improvements can be made to the invention without departing from the scope thereof.

What is claimed is:

- 1 1. A graft delivery system comprising:
 - 2 a) a catheter having:
 - 3 i) an elongated shaft with a first outer diameter; and
 - 4 ii) a delivery base on a distal portion of the catheter
 - 5 shaft which has a second outer diameter, larger than the first
 - 6 outer diameter;
 - 7 b) an aortic graft in a compressed state with proximal and
 - 8 distal ends and mounted on the catheter shaft proximally adjacent to
 - 9 the delivery base;
 - 10 c) an expandable anchoring member which is mounted on
 - 11 the delivery base and is secured to the distal end of the graft by a butt-
 - 12 joint attachment means; and
 - 13 d) means on the delivery base for expanding the anchoring
 - 14 member.
- 1 2. The graft delivery system of claim 1 wherein the means for
- 2 expanding the anchoring member includes an inflatable member located on
- 3 the delivery base.
- 1 3. The graft delivery system of claim 2 including an inflation lumen
- 2 extending through the catheter shaft in fluid communication with the interior
- 3 of the inflatable member and the inflation lumen.

1 4. The graft delivery system of claim 1 wherein the diameter of the
2 delivery base is from about 1.1 to about 4.0 times greater than the diameter
3 of the catheter shaft.

1 5. The graft delivery system of claim 4 wherein the diameter of the
2 delivery base is from about 2.0 to about 2.5 times greater than the diameter
3 of the catheter shaft.

1 6. The graft delivery system of claim 1 wherein the system has an
2 outer diameter of less than about 7 mm.

1 7. The graft delivery system of claim 1 wherein the anchoring
2 member comprises a stent.

1 8. The graft delivery system of claim 1 wherein the butt-joint
2 attachment means comprises a plurality of staples radially disposed around
3 the anchoring member having means for engaging the graft.

1 9. The graft delivery system of claim 8 wherein the means for
2 engaging the graft comprise hooks.

1 10. The graft delivery system of claim 8 wherein the means for
2 engaging the graft comprise T-bars.

1 11. The graft delivery system of claim 7 wherein the butt-joint
2 attachment means comprises a plurality of graft ribbons extending from the
3 distal end of the graft wound through the anchoring member.

1 12. The graft delivery system of claim 1 wherein the butt-joint
2 attachment means comprises a plurality wires woven into the graft and
3 secured to the anchoring member.

1 13. The graft delivery system of claim 1 wherein the anchoring
2 member comprises a stent having proximal and distal ends and a plurality of
3 sinusoidal circular expanding members and wherein the butt-joint attachment
4 means comprises:
5 a) a plurality of staples having means for engaging the graft;
6 b) a first expanding member positioned such that at least a
7 second expanding member is between the first expanding member and
8 the proximal end of the anchoring member; and
9 c) the staples attached to the first expanding member such
10 that expansion of the first expanding member causes the staples to pull
11 the distal end of the graft over the second expanding member.

1 14. The graft delivery system of claim 13 wherein the stent is
2 configured so that when the stent expands, the distal end expands before the
3 proximal end.

1 15. The graft delivery system of claim 13 wherein the means for
2 expanding the stent expands the distal end of the stent before the proximal
3 end.

1 16. A graft delivery system comprising:
2 a) a catheter having an elongated shaft and a relatively small
3 outer diameter;
4 b) a delivery base on a distal portion of the catheter shaft
5 which has a relatively large diameter;
6 c) a prosthetic assembly comprising an aortic graft in a
7 compressed state with proximal and distal ends and a self-expanding
8 anchoring member which is secured to the distal end of the graft by a
9 butt-joint attachment means; and
10 d) the assembly disposed on the catheter such that the graft
11 is disposed on the catheter shaft without overlapping the delivery base
12 and the anchoring member is disposed on the delivery base.

1 17. The graft delivery system of claim 16 wherein the self-expanding
2 anchoring member is formed from shape-memory material.

1 18. The graft delivery system of claim 17 wherein the anchoring
2 member is formed from a NiTi alloy.

1 19. A catheter for delivering a graft comprising:

- 2 a) a catheter having an elongated shaft and a first outer
3 diameter;
4 b) a delivery base on a distal portion of the catheter shaft
5 which has a second diameter, larger than the first diameter; and
6 c) means on the delivery base for deploying the graft within
7 the aorta.

1 20. The catheter of claim 19 wherein the deploying means comprises
2 an inflatable balloon.

1 21. The catheter of claim 20 including an inflation lumen extending
2 through the catheter shaft in fluid communication with the interior of the
3 inflatable balloon and the inflation lumen.

1 22. The catheter of claim 19 the diameter of the delivery base is
2 from about 1.1 to about 4.0 times greater than the diameter of the catheter
3 shaft.

1 23. The catheter of claim 22 wherein the diameter of the delivery
2 base is from about 2.0 to about 2.5 times greater than the diameter of the
3 catheter shaft.

1 24. A prosthetic assembly comprising an aortic graft in a
2 compressed state with proximal and distal ends and an expandable anchoring

3 member which is secured to the distal end of the graft by a butt-joint
4 attachment means.

1 25. The prosthetic assembly of claim 24 wherein the anchoring
2 member is self-expanding.

1 26. The prosthetic assembly of claim 25 wherein the anchoring
2 member is formed from shape-memory material.

1 27. The prosthetic assembly of claim 26 wherein the anchoring
2 member is formed from a NiTi alloy.

1 28. The prosthetic assembly of claim 24 wherein the butt-joint
2 attachment means comprises a plurality of staples radially disposed around
3 the anchoring member having means for engaging the graft.

1 29. The prosthetic assembly of claim 28 wherein the means for
2 engaging the graft comprise hooks.

1 30. The prosthetic assembly of claim 28 wherein the means for
2 engaging the graft comprise T-bars.

1 **31.** The prosthetic assembly of claim 24 wherein the butt-joint
2 attachment means comprises a plurality of graft ribbons extending from the
3 distal end of the graft wound through the anchoring member.

1 **32.** The prosthetic assembly of claim 24 wherein the butt-joint
2 attachment means comprises a plurality of wires woven into the graft and
3 secured to the anchoring member.

1 **33.** The prosthetic assembly of claim 24 wherein the butt-joint
2 attachment means causes longitudinal movement of the graft when the
3 anchoring member is expanded.

1 **34.** The prosthetic assembly of claim 33 wherein the anchoring
2 member comprises a stent having proximal and distal ends, a first sinusoidal
3 circular expanding member more proximal to the graft than a second
4 sinusoidal expanding member, and the butt-joint attachment means secured
5 to the second sinusoidal expanding member so that when the second
6 sinusoidal expanding member expands it causes longitudinal movement of the
7 graft which pulls the distal end of the graft over the first sinusoidal expanding
8 member.

1 **35.** The prosthetic assembly of claim 34 wherein the butt-joint
2 attachment means comprises a plurality of staples radially disposed around

3 the second sinusoidal expanding member having means for engaging the
4 graft.

1 36. The prosthetic assembly of claim 34 wherein the anchoring
2 member is configured so that when the anchoring member expands, the distal
3 end expands before the proximal end.

1 37. The prosthetic assembly of claim 34 wherein the anchoring
2 member comprises a self-expanding stent.

1 38. A kit for deploying a graft to repair a portion of a patient's aorta
2 comprising:

3 a) a delivery catheter comprising a catheter having an
4 elongated shaft and a first outer diameter, a delivery base on a distal
5 portion of the catheter shaft having a second diameter which is larger
6 than the first diameter, and means for deploying the graft within the
7 aorta.

8 b) an aortic graft which has proximal and distal ends and
9 which is configured to be disposed about the catheter shaft when in a
10 compressed state; and

11 c) an expandable anchoring member which is secured to the
12 distal end of the graft by butt-joint attachment means and which is
13 configured to be disposed on the delivery base on the catheter shaft.

1 39. The kit of claim 38 wherein the deploying means comprises an
2 inflatable balloon.

1 40. The kit of claim 39 wherein the delivery catheter includes an
2 inflation lumen extending through the catheter shaft in fluid communication
3 with the interior of the inflatable balloon and the inflation lumen.

1 41. The kit of claim 38 wherein the diameter of the delivery base is
2 from about 1.1 to about 4.0 times greater than the diameter of the catheter
3 shaft.

1 42. The kit of claim 38 wherein the graft and anchoring means
2 disposed on the delivery catheter have an insertion diameter of less than
3 about 7 mm.

1 43. The kit of claim 38 wherein the butt-joint attachment means
2 comprises a plurality of staples radially disposed around the anchoring
3 member having means for engaging the graft.

1 44. The kit of claim 43 wherein the means for engaging the graft
2 comprise hooks.

1 45. The kit of claim 43 wherein the means for engaging the graft
2 comprise T-bars.

1 46. The kit of claim 38 wherein the butt-joint attachment means
2 comprises a plurality of graft ribbons extending from the distal end of the
3 graft wound through the anchoring member.

1 47. The kit of claim 38 wherein the butt-joint attachment means
2 comprises a plurality of wires woven into the graft and secured to the
3 anchoring member.

1 48. The kit of claim 38 wherein the anchoring member comprises a
2 stent having proximal and distal ends and a plurality of sinusoidal circular
3 expanding members and wherein the butt-joint attachment means comprises:
4 a) a plurality of staples having means for engaging the graft;
5 b) a first expanding member positioned such that at least a
6 second expanding member is between the first expanding member and
7 the proximal end of the anchoring member; and
8 c) the staples attached to the first expanding member such
9 that expansion of the first expanding member causes the staples to pull
10 the distal end of the graft over the second expanding member.

1 49. The kit of claim 48 wherein the anchoring member is configured
2 so that when the anchoring member expands, the distal end expands before
3 the proximal end.

1 50. The kit of claim 48 wherein the means for expanding the
2 anchoring member expands the distal end of the anchoring member before
3 the proximal end.

1 51. A kit for repairing a portion of a patient's vasculature comprising:
2 a) a delivery catheter comprising a catheter having an
3 elongated shaft and a relatively small outer diameter, a delivery base on
4 a distal portion of the catheter shaft which has a relatively large
5 diameter, and means on the delivery base for anchoring the graft within
6 the aorta.
7 b) an aortic graft which has proximal and distal ends and
8 which is configured to be disposed about the catheter shaft when in a
9 compressed state; and
10 c) a self-expanding anchoring member which is secured to
11 the distal end of the graft by butt-joint attachment means and which is
12 configured to be disposed on the delivery base on the catheter shaft.

1 52. The kit of claim 51 wherein the self-expanding anchoring
2 member is formed from shape-memory material.

1 53. The kit of claim 52 wherein the anchoring member is formed
2 from a NiTi alloy.

- 1 **54.** A method for repairing a portion of a patient's vasculature
2 comprising the steps of:
- 3 a) providing a catheter assembly having:
- 4 1) a catheter comprising an elongated shaft with a
5 first outer diameter;
- 6 2) a delivery base on a distal portion of the catheter
7 shaft which has a second diameter, larger than the first
8 diameter; and
- 9 3) a prosthetic assembly comprising an aortic graft in a
10 compressed state with proximal and distal ends and an
11 expandable anchoring member which is secured to the distal end
12 of the graft by a butt-joint attachment means, the assembly
13 disposed on the catheter such that the graft is disposed on the
14 catheter shaft without overlapping the delivery base and the
15 anchoring member is disposed on the delivery base; and
- 16 b) advancing the catheter assembly with the prosthetic
17 assembly to the desired location in the patient's vasculature; and
- 18 c) deploying the prosthetic assembly within the patient's
19 vasculature.

- 1 **55.** The method for repairing a portion of a patient's vasculature of
2 claim 54 wherein the anchoring member comprises a stent with proximal and
3 distal ends and a plurality of sinusoidal circular expanding members and
4 wherein the butt-joint attachment means comprises:

- 5 a) a plurality of staples having means for engaging the graft;
- 6 b) a first expanding member positioned such that at least a
- 7 second expanding member is between the first expanding member and
- 8 the proximal end of the anchoring member; and
- 9 c) the staples attached to the first expanding member such
- 10 that expansion of the first expanding member causes the staples to pull
- 11 the distal end of the graft over the second expanding member,
- 12 further comprising the step of expanding the stent so that the distal end of
- 13 the graft is pulled over the second expanding member.

1 56. The method for repairing a portion of a patient's vasculature of

2 claim 55 wherein the distal end of the anchoring member is expanded before

3 the proximal end.

- 1 57. A method for repairing a portion of a patient's vessel comprising
- 2 the steps of:
- 3 a) providing a prosthetic assembly comprising a graft having
- 4 proximal and distal ends and an expandable anchoring member having
- 5 proximal and distal ends with the distal end of the graft secured to the
- 6 proximal end of the anchoring member;
- 7 b) deploying the prosthetic assembly at a desired location in
- 8 a patient's vessel; and

9 b) deploying a second expandable anchoring member
10 coaxially within the prosthetic assembly so that the second anchoring
11 member seals a distal portion of the graft against the patient's vessel.

1 58. The method for repairing a portion of a patient's vessel of claim
2 57 further comprising the step of deploying the second anchoring member so
3 that it extends past the distal end of the first anchoring member.

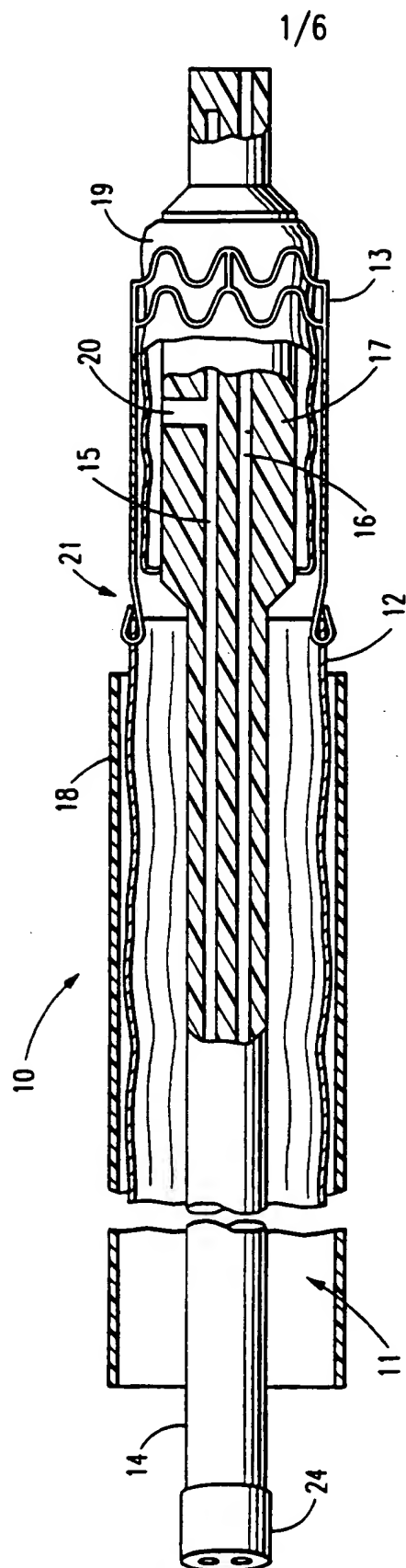


FIG. 1

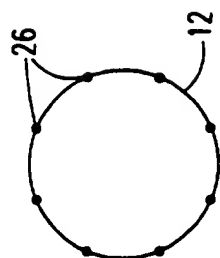


FIG. 2a



FIG. 3a

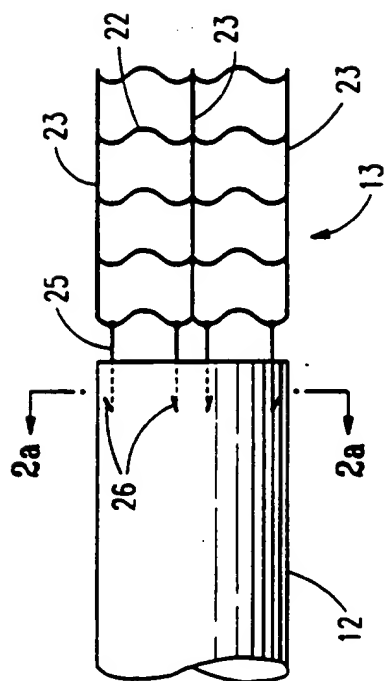


FIG. 2

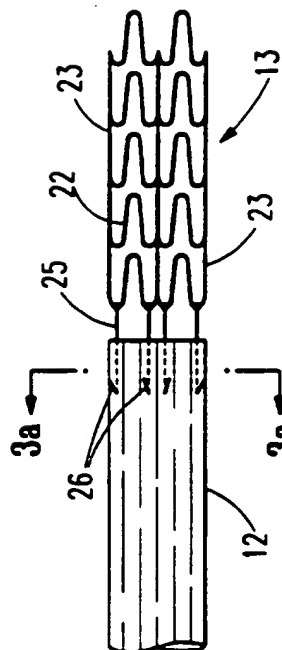


FIG. 3

FIG. 4a

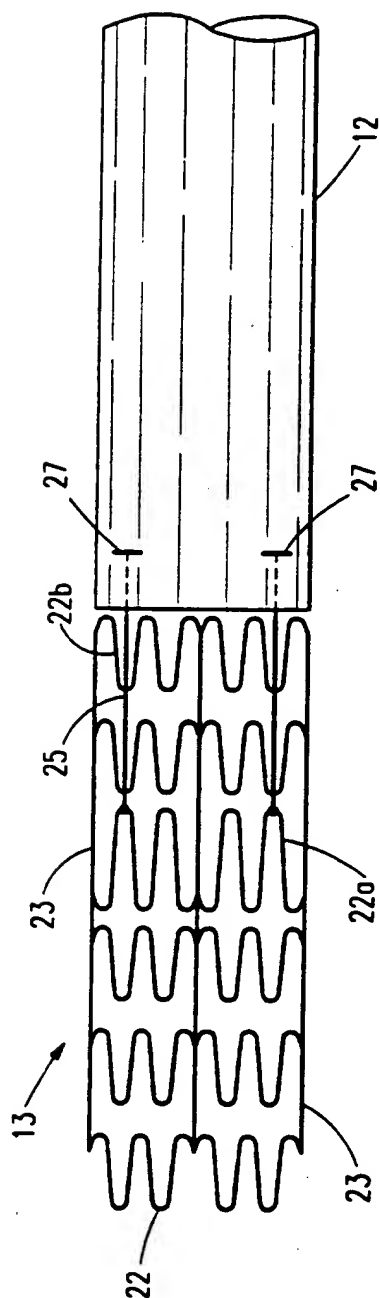


FIG. 4b

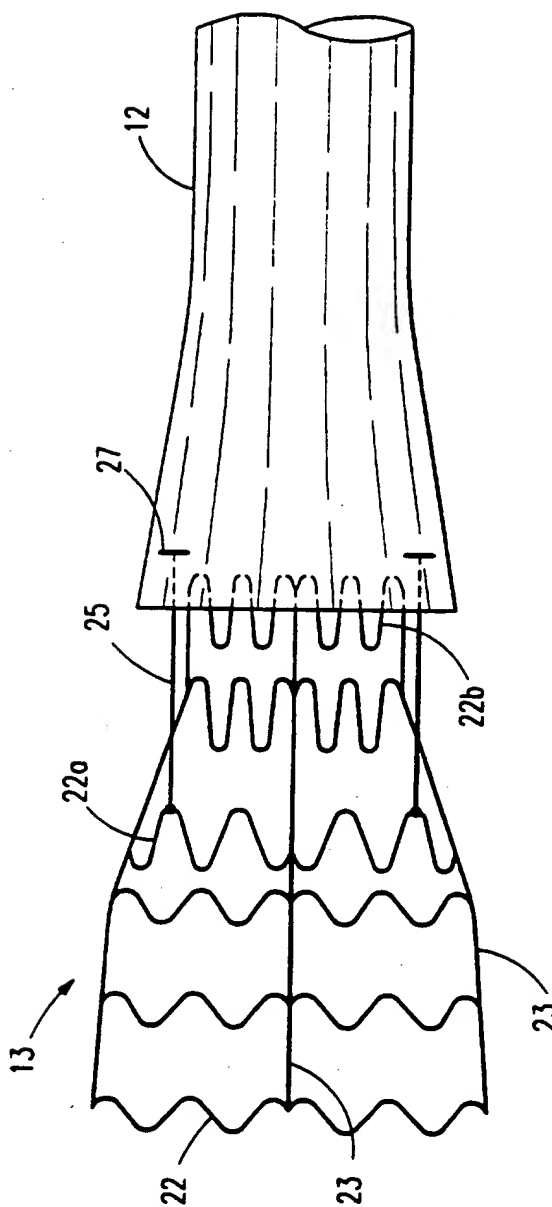


FIG. 4c

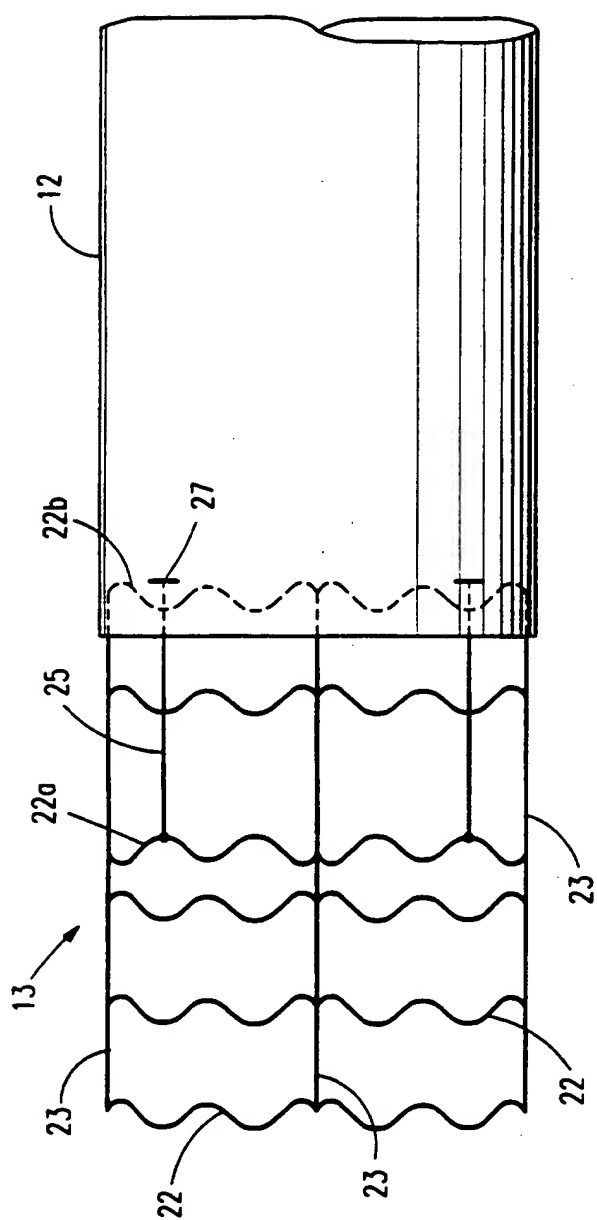
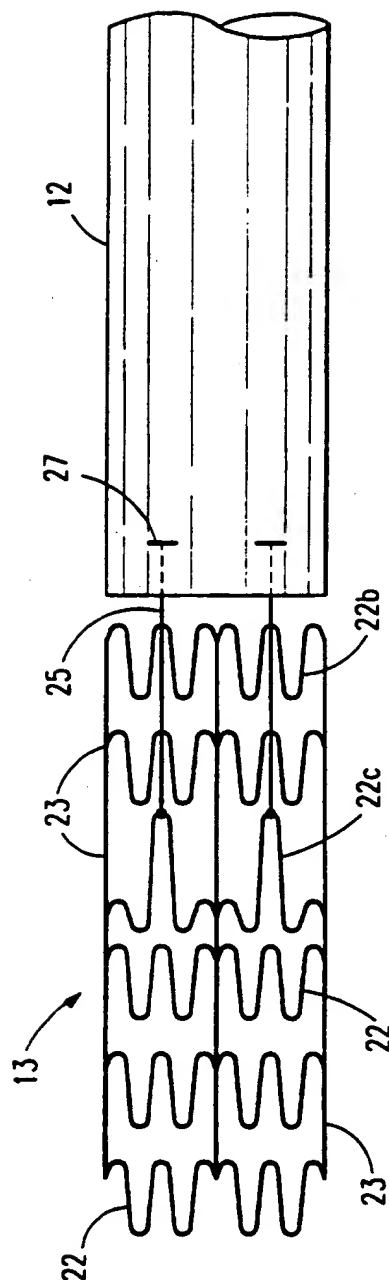


FIG. 4d



5/6

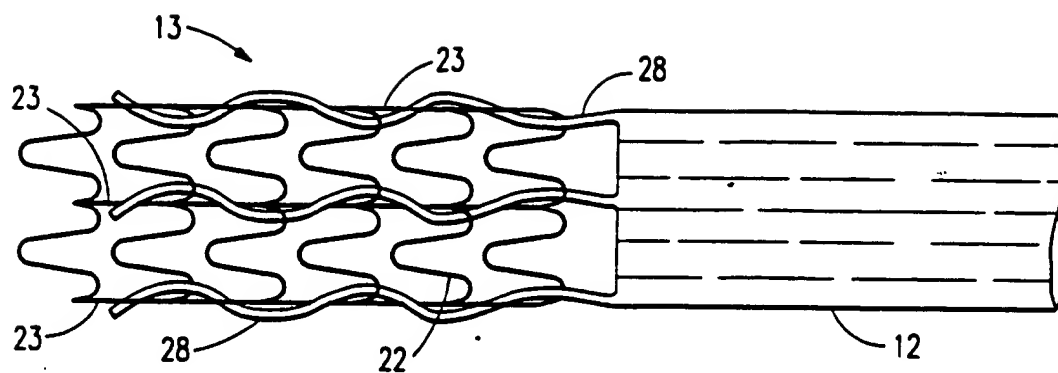


FIG. 5

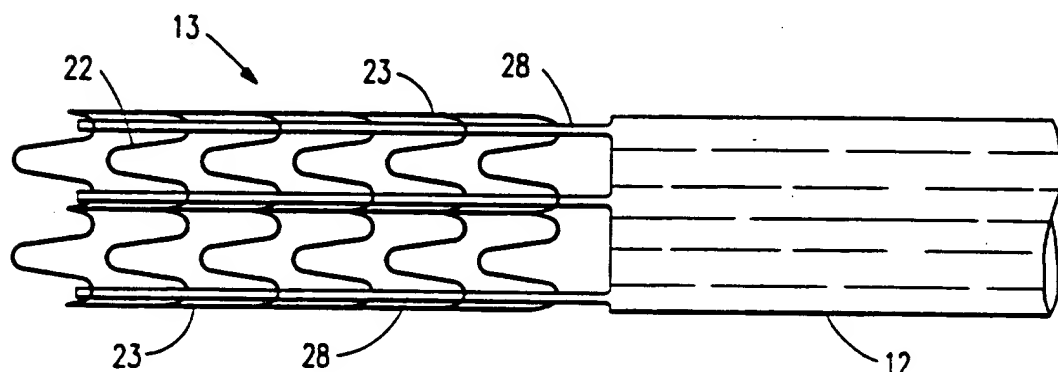


FIG. 6

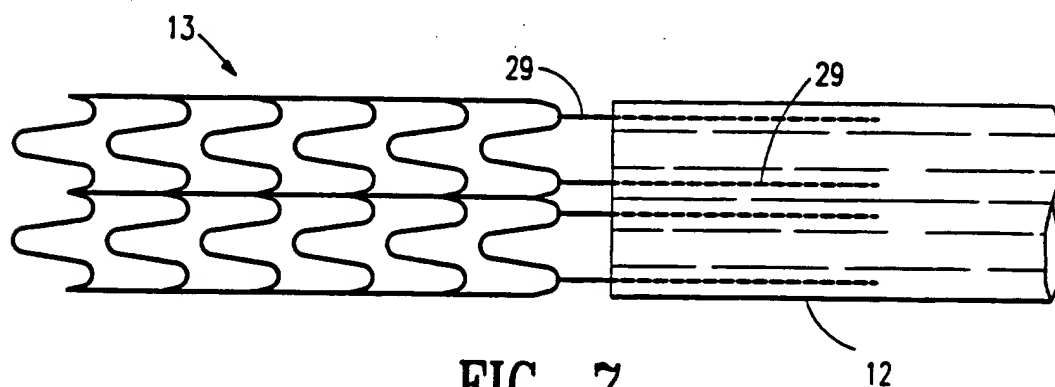


FIG. 7

6/6

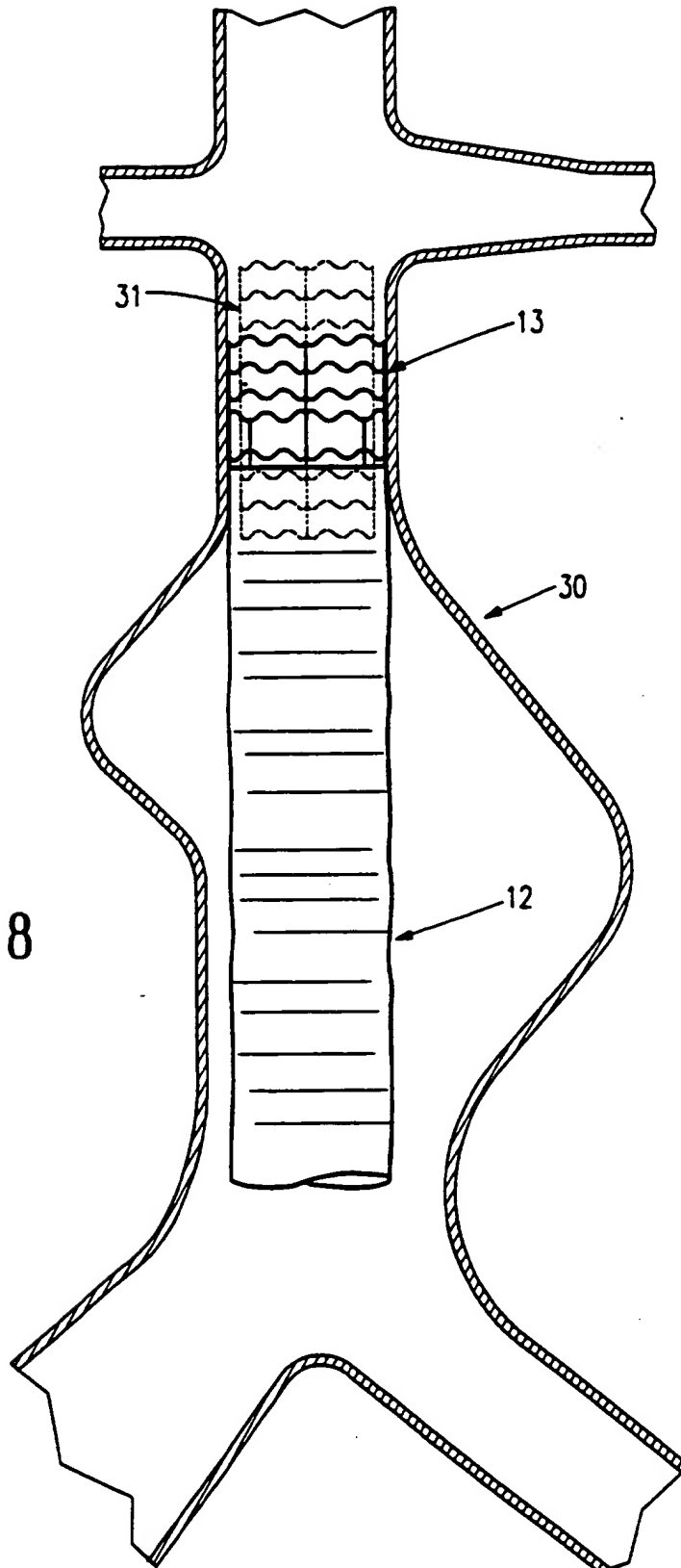


FIG. 8

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 95/14535

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 6 A61F2/02 A61F2/06 A61F2/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A,5 102 417 (EXPANDABLE GRAFTS PARTNERSHIP) 7 April 1992 see column 9 - column 10; figures 3,4 ---	19-21
X	US,A,4 793 348 (PALMAZ J.C.) 27 December 1988 see column 8, line 47-59; figure 3 ---	19-21
A	US,A,5 104 399 (ENDOVASCULAR TECHNOLOGIES) 14 April 1992 see column 2-5; figures 1,2,6,7 ---	1-3,16, 38-40,51
A	EP,A,0 466 518 (HARRISON MEDICAL TECHNOLOGIES, INC.) 15 January 1992 see column 2 see column 10-11 see column 14; figures 1,10,14,15 --- -/--	1-3,16, 38-40,51

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

22 March 1996

Date of mailing of the international search report

'12 04, 08

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax: (+31-70) 340-3016

Authorized officer

Bichlmayer, K-P

INTERNATIONAL SEARCH REPORT

Internal . Application No

PCT/US 95/14535

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP,A,0 621 016 (C.R.BARD, INC.) 26 October 1994 see column 3, line 16-30 see column 5, line 53 - column 6, line 19 see column 8, line 6-15 see figures 1,4,10 ---	24,25
Y	GB,A,2 269 104 (TAHA ROUDAN LAZIM) 2 February 1994 see page 5 - page 6 see figure 1 ---	24,25
Y	EP,A,0 421 729 (MEDTRONIC, INC.) 10 April 1991 see column 1, line 47-52 see column 5, line 43-50; figures 1,4,6 -----	24,25

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 95/14535

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

The international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 54-58
because they relate to subject matter not required to be searched by this Authority, namely:
Please see Rule 39.1(1v) PCT.
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internat. Application No

PCT/US 95/14535

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-5102417	07-04-92	US-A- 4733665	29-03-88
		AU-B- 633478	04-02-93
		AU-B- 3174289	28-09-89
		CA-A- 1330186	14-06-94
		EP-A,B 0335341	04-10-89
		JP-A- 1299550	04-12-89
		AU-B- 591942	21-12-89
		AU-B- 6488286	14-05-87
		CA-A- 1281504	19-03-91
		CA-A- 1281505	19-03-91
		EP-A,B 0221570	13-05-87
		JP-A- 4357949	10-12-92
		JP-C- 1719657	14-12-92
		JP-B- 4006377	05-02-92
		JP-A- 62231657	12-10-87
		US-A- 4776337	11-10-88
		US-A- 4739762	26-04-88

US-A-4793348	27-12-88	NONE	

US-A-5104399	14-04-92	US-A- 4787899	29-11-88
		AU-B- 637318	27-05-93
		AU-B- 3439289	05-10-89
		AU-B- 663583	12-10-95
		AU-B- 3826193	01-07-93
		CA-A- 1335528	16-05-95
		EP-A- 0407425	16-01-91
		EP-A- 0688544	27-12-95
		JP-T- 3503246	25-07-91
		WO-A- 8908433	21-09-89
		US-A- 5397345	14-03-95
		US-A- 5275622	04-01-94

EP-A-466518	15-01-92	US-A- 5275622	04-01-94
		AT-T- 134497	15-03-96
		AU-B- 7020494	06-10-94
		AU-B- 649051	12-05-94
		AU-B- 8041791	16-01-92
		CA-A- 2046974	14-01-92
		EP-A- 0680734	08-11-95

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internat. Application No

PCT/US 95/14535

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-466518		JP-A- 5076554	30-03-93
EP-A-621016	26-10-94	AU-B- 5939794	27-10-94
		CA-A- 2121858	23-10-94
		JP-A- 6343703	20-12-94
GB-A-2269104	02-02-94	NONE	
EP-A-421729	10-04-91	CA-A- 2026604	03-04-91
		DE-D- 69024901	29-02-96
		JP-A- 3151983	28-06-91

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☒ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.